UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: July 13, 2020

SUBJECT: Efficacy Review for ACCEL (CONCENTRATE) DISINFECTANT CLEANER, EPA Reg. No. 74559-4
DP Barcode: 458077
E-submission No. 46872

FROM: Nicole Karikari
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Date Signed: July 23, 2020

Thao Pham

TO: Joseph Varco RM 33, PM Perri Moeller
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Virox Technologies, Inc.
2770 Coventry Road
Oakville, Ontario L6H 6R1 Canada

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	4.25%
Other Ingredients	95.75%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Concentrated Liquid (Dilutable)

Submission type: Label Amendment

Currently registered efficacy claim(s): Disinfectant (bactericidal, virucidal, and fungicidal) and non-food contact sanitizer for use on hard, non-porous surfaces in healthcare, residential, commercial, industrial, institutional, veterinary, and agricultural environments.

Requested action(s): Addition of bactericidal and virucidal claims, and bactericidal stability claims of use solution (1:64) for up to 90 days

Documents considered in this review:

- Cover letter from applicant to EPA dated 2/14/2020
- Proposed label dated 1/31/2020
- Data Matrix (EPA Form 8570-35) dated 2/14/2020
- Four efficacy studies
    - MRID 51041604 dated 1/3/2019
    - MRID 51041605 dated 12/23/2019
    - MRID 51041606 dated 12/18/2018
    - MRID 51041607 dated 12/18/2018
- Efficacy Review for DP 390699 dated 8/23/2011
    - MRID 48138210 dated 5/26/2010
    - MRID 48138211 dated 5/26/2010
    - MRID 48138212 dated 5/26/2010
- Confidential Statement of Formula (EPA Form 8670-4)
    - Basic Formulation dated 1/17/2020
    - Alternate Formulation 1 dated 1/17/2020
    - Alternate Formulation 2 dated 1/17/2020
    - Alternate Formulation 3 dated 1/17/2020
    - Alternate Formulation 4 dated 1/17/2020

II PROPOSED DIRECTIONS FOR USE

"**[+++] For Use as a One-Step Bactericide Cleaner/Disinfectant:** Dilute at 2.0 oz of product per gallon of water (Dilute at 1:64)
1. Pre-clean visibly soiled areas.
2. Spray Use Solution until thoroughly wet.
3. Let stand for ten (10) minutes.
4. (Wipe surfaces dry) (or rinse). (If streaking is observed, wipe with a clean, damp [cloth or] [microfiber cloth or] [paper towel]. (Allow to air dry [Let air dry])."

III STUDY SUMMARIES

1.	**MRID**	51041604		
Study Objective		Disinfectant - Bactericidal		
Testing Lab; Lab Study ID		Bioscience Laboratories, Inc.; 1809407-204		
Experimental Start Date		12/6/2018	**Study Completion Date:**	1/3/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Bordetella bronchiseptica* (ATCC 4617)		
Test Method		AOAC 961.02, Germicidal Spray Products as Disinfectants (2013)		
Application Method		Liquid spray; Sprayed 3 times at distance of 6 to 8 inches from test carrier		
Test Substance Preparation	**Name/ID**	Accel Concentrate (EPA Reg. No. 74559-4)		
	Lots **☐ 1 ☒ 2 ☐ 3**	13659 13660		
	Preparation	Tested concentration: Nominal Tested Dilution: 1:64 dilution Diluent: 10 ml test product + 640 ml 200 ppm unsoftened water		
Soil load		Heat-Inactivated Fetal Bovine Serum (FBS), 5% (v/v)		
Carrier type, # per lot		Steam-heat sterilized glass slides; 10 carriers per lot		
Test conditions		Contact time: 10 minutes Temperature: 17.9 – 22.0°C Relative humidity: N/A		
Neutralizer		20 ml Letheen Broth + catalase (~ 10^3 units/ml)		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Deviation: Section 10.2 of the protocol states, “The plates will be placed in a 36 ± 1 °C incubator for 30 to 40 minutes to allow the carriers to dry”. On 12/16/2018, the inoculated carriers were placed in a 36 ± 1 °C incubator and allowed to dry for only 21 minutes as the carriers were “visibly dry” after that time. (See page 11.)		

2.	**MRID**	51041605		
Study Objective		Disinfectant - Virucidal		
Testing Lab; Lab Study ID		Institutio Nacional de Investigacion yTecnologia Agraria y Alimentaria (INIA); 18CISA093.1		
Experimental Start Date		10/25/2019	**Study Completion Date:**	12/23/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		African Swine Fever Virus (ASFV), Strain BA71V (obtained from the World Reference Laboratory for ASFV)		
Indicator Cell Culture		Vero (African green monkey kidneys) cells (ATCC CCL-81)		
Test Method		Protocol number 18CISA093.1		
Application Method		Liquid application		
Test Substance Preparation	**Name/ID**	Intervention Concentrate		
	Lots **☐ 1 ☒ 2 ☐ 3**	13829 13830		
	Preparation	Tested concentration: LCL Tested Dilution: 1:64 dilution		

		Diluent: 0.5 ml test substance + 32 ml 400 ppm (388 ppm) AOAC synthetic hard water
Soil load		5% FBS
Carrier type, # per lot		Sterilized glass Petri plate; 1 per lot
Test conditions		Contact time: 5 minutes Temperature: 22°C Relative humidity: 41%
Neutralizer		Letheen Broth medium + 0.1% Sodium Thiosulfate
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		1. Due to the unavailability of GLP testing for this virus, the agency has previously advised that non-GLP testing will be considered, provided that the testing be designed to replicate GLP conditions and any deviations be clearly noted for review. 2. “Intervention Concentrate” and “Oxyteam” (listed on CoAs) were not listed as registered alternative brand names for this product.

3.	**MRID**	51041606		
Study Objective		Disinfectant - Virucidal		
Testing Lab; Lab Study ID		Bioscience Laboratories, Inc.; 1809402-404C.01		
Experimental Start Date		11/20/2018	**Study Completion Date:**	12/18/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Canine Influenza A H3N2 (USDA NVSL#004-IDV) (Source: United States Department of Agriculture, National Veterinary Services Laboratories))		
Indicator Cell Culture		MDCK cells, (ATCC CCL-34)		
Test Method		ASTM E1053-11, Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surface and the Official Methods of Analysis; Protocol number 189402-404		
Application Method		Liquid application		
Test Substance Preparation	**Name/ID**	Accel Concentrate (EPA Reg. No. 74559-4)		
	Lots **☐ 1 ☒ 2 ☐ 3**	13659 13660		
	Preparation	Tested concentration: LCL Tested Dilution: 1:64 dilution Diluent: 0.5 ml test substance + 32 ml 200 ppm (202 ppm) filter sterilized Tap Water		
Soil load		5% FBS		
Carrier type, # per lot		Sterilized glass Petri plate; 1 per lot		
Test conditions		Contact time: 5 minutes Temperature: 22.3 – 22.9°C Relative humidity: N/A		
Neutralizer		Dey-Engley (D/E) Broth + 1% Catalase		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A		

4.	**MRID**	51041607		
Study Objective		Disinfectant - Virucidal		
Testing Lab; Lab Study ID		Bioscience Laboratories, Inc.; 1809402-404D.01		
Experimental Start Date		11/20/2018	**Study Completion Date:**	12/18/2018
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Feline Leukemia Virus strain CT600 (ATCC VR-1373)		
Indicator Cell Culture		CRFK cells (ATCC CCL-94)		
Test Method		ASTM E1053-11, Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surface and the Official Methods of Analysis; Protocol number 189402-404		
Application Method		Liquid application		
Test Substance Preparation	**Name/ID**	Accel Concentrate (EPA Reg. No. 74559-4)		
	Lots **☐ 1 ☒ 2 ☐ 3**	13659 13660		
	Preparation	Tested concentration: LCL Tested Dilution: 1:64 dilution Diluent: 2.0 ml test substance + 128 ml 200 ppm (202 ppm) filter sterilized Tap Water		
Soil load		5% FBS		
Carrier type, # per lot		Sterilized glass Petri plate; 1 per lot		
Test conditions		Contact time: 5 minutes Temperature: 22.3 – 22.9°C Relative humidity: N/A		
Neutralizer		Dey-Engley (D/E) Broth + 1% Catalase		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A		

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	Organism	Contact Time	Dilution	Results		Population Control Average Log_{10} CFU/ carrier
				Lot No.	No. Exhibiting Growth/ Total No. Tested	
5% organic load present						
51041604	*Bordetella bronchiseptica* (ATCC 4617)	10 minutes	1:64 dilution	13659	0/10	5.80
				13660	0/10	

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
5 minutes, 1:64 dilution, 5% soil load					
51041605	African Swine Fever Virus (ASFV), Strain BA71V	Lot No.	13829	13830	5.1
		10^{-2} to 10^{-6} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤ 0.5	≤ 0.5	
		Log Reduction	≥ 4.6	≥ 4.6	
51041606	Canine Influenza A H3N2 (USDA NVSL#004-IDV)	Lot No.	13659	13660	6.25
		10^{-2} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤ 1.50	≤ 1.50	
		Log Reduction	≥ 4.75	≥ 4.75	
51041607	Feline Leukemia Virus strain CT600 (ATCC VR-1373)	Lot No.	13659	13660	5.50
		10^{-2} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤ 1.50	≤ 1.50	
		Log Reduction	≥ 4.00	≥ 4.00	

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51041604	Disinfectant, bactericidal	Hard non-porous surface	Liquid spray; 1:64 dilution	10 minutes	5%	200 ppm unsoftened water	• *Bordetella bronchiseptica* (ATCC 4617)	**Yes**
51041605	Disinfectant, virucidal	Hard non-porous surface	Liquid application; 1:64 dilution	5 minutes	5%	400 ppm AOAC synthetic hard water	• African Swine Fever Virus (ASFV), Strain BA71V	**No.** "Intervention Concentrate" and "Oxyteam" (listed on CoAs) were not listed as registered alternative brand names for this product. Additional information will be needed to confirm the identity of the test substance.
51041606, 51041607	Disinfectant, virucidal	Hard non-porous surface	Liquid application; 1:64 dilution	5 minutes	5%	200 ppm filter sterilized Tap Water	• Canine Influenza A H3N2 (USDA NVSL#004-IDV) • Feline Leukemia Virus strain CT600 (ATCC VR-1373)	**Yes**
48138210, 48138211, 48138212 (2010)	Disinfectant, bactericidal – lengthened use-solution (10-90 days)	Hard non-porous surface	Liquid application; 1:64 dilution	5 minutes	5%	200 ppm hard water	• *Staphylococcus aureus* (ATCC 6538) • *Salmonella enterica* (ATCC 10708) • *Pseudomonas aeruginosa* (ATCC 15442)	**No.** Data only substantiates efficacy label claims for a 10-90 day old aged, 1:16 use solution of the product.

VI LABEL COMMENTS

Label Date/Identification Number: 1/31/2020

1. The proposed label claims that the product, ACCEL (CONCENTRATE) DISINFECTANT CLEANER, EPA Reg. No. 74559-4, when diluted at 2 fl. oz. per gallon of 200 ppm hard water (1:64 dilution), is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil:

   - For a 10-minute contact time:

     Bordetella bronchiseptica (ATCC 4617)

   - For a 5-minute contact time:

     Canine Influenza A H3N2 (USDA NVSL#004-IDV)
     Feline Leukemia Virus strain CT600 (ATCC VR-1373)

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, ACCEL (CONCENTRATE) DISINFECTANT CLEANER, EPA Reg. No. 74559-4, when diluted at 2 fl. oz. per gallon of 400 ppm hard water, is an effective disinfectant with virucidal activity against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 5-minute contact time:

   African Swine Fever Virus (ASFV), Strain BA71V

   These claims are **not acceptable**. The test substances used in the study, "Intervention Concentrate" and "Oxyteam" (listed on CoAs), are not listed as registered alternative brand names for this product. Additional information will be needed to confirm the identity of the test substance.

3. The proposed label claims that a 10-90 day old aged 1:64 use solution of the product is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 200 ppm hard water and 5% serum for a 5-minute contact time:

   Staphylococcus aureus (ATCC 6538)
   Salmonella enterica (ATCC 10708)
   Pseudomonas aeruginosa (ATCC 15442)

   This claim is **not acceptable** as it is not supported by the cited data. The cited data only substantiates efficacy label claims for a 10-90 day old aged at a 1:16 use solution of the product.

4. In addition, please provide an updated Terms of Registration to support Emerging Viral Pathogen claims.

a. The Terms of Registration should be dated, have the product name and registration number, and include the following statement:

"Per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels', Virox Technologies, Inc. agrees to the following terms of registration:"

followed by the four statements from Appendix I of the guidance. Ensure that statements under Item 2 are specific to hard, nonporous surfaces.

b. Include the following emerging viral pathogens table:

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Poliovirus Type 1 (Strain Brunhilde)
Large, non-enveloped virus	Poliovirus Type 1 (Strain Brunhilde)
Small, non-enveloped virus	Poliovirus Type 1 (Strain Brunhilde), Rhinovirus type 37

5. Make the following changes to the proposed label:
   a. Throughout the label,
      i. Remove or qualify one-step claims that refer to disinfection or sanitization and cleaning/deodorizing such as "(One step) disinfectant cleaner (and deodorant)", "cleans, disinfects, (&) deodorizes" with: "when use-directions for disinfection are followed" or "when used according to disinfection directions". Additionally, remove or revise "one step cleaner" and similar claims. "One-step" claims are reserved for disinfection or sanitization claims when tested against a minimum 5% soil load.

      ii. Revise "thoroughly wet" to "visibly wet" as "visibly" is a more distinct indicator for end users.

      iii. Remove or qualify each instance of "Pseudomonacidal" and "Parvocidal" with the specific strains tested as these existing terms may imply efficacy against the entire genus. Note, footnote *1 used intermittently on the label for Parvocidal is incorrect.

   b. On page 1,
      i. Remove "Parvocidal".

   c. On page 2 and throughout the label,
      i. Remove or revise "Homecare", "Healthcare", Veterinary", "Aquaculture", "Personal services", Transportation", and "Aviation" with "for use on hard nonporous surfaces in" as these are not use sites or surfaces.

      ii. Remove brackets from "Clinics" to clarify use sites or surfaces.

   d. On page 3,

i. Remove “Catastrophic events and gross contamination” as this claim is misleading.

e. On page 4,
   i. Revise “Safe to use on floors” to “Safe to use on sealed floors”.
   ii. Remove “Meets USP (<1072>) Standards for Disinfectants”.

f. On page 5,
   i. Remove “For high risk, high contamination areas” as this claim may be misleading.

   ii. Remove “A effective One-step sanitizer-cleaner”.

g. On page 6 and throughout the label,
   i. Remove “(of Ready to Use) (RTU) disinfectant (sanitizer)…” as this claim may be confusing to end-users.

h. On page 7,
   i. Remove “Bactericidal, *Virucidal, and Pseudomonacidal in 1 minute” as this contact time claim is not applicable to all the bacteria and viruses listed on the label. Data have not been submitted to substantiate this claim.

   ii. Revise “Kills flu virus” to “Kills Influenza A virus (H1N1) which may cause the flu”.

   iii. Remove parenthesis around “(99.9% of)” from the disinfection qualifier or remove “[Eliminates]”.

i. On page 9,
   i. Remove “any” from “any hard non-porous…” as use sites and surfaces are limited to those listed on the label.

j. On page 13,
   i. Remove references to “FDA” and “OSHA” as this may imply endorsement.

k. On page 14,
   i. Remove “highly” from “highly effective” as this may imply heightened efficacy.

l. On page 15,
   i. Remove “[1:64]” from under “Bacterial Stability of the Use-Solution”.

m. On page 23,
   i. remove application for use as an “electrostatic sprayer”. Data are needed to substantiate this application.

n. On page 25,
   i. Remove or revise “high risk quarantine areas” and “confirmed disease/outbreak conditions” from the table as these claims may be misleading to the end user.

o. On page 31,
    i. Toilet bowl use directions should specify adding 8 oz. of the product to the toilet bowl volume rather than “empty toilet bowls”.

p. On page 38,
    i. For ** footnote, remove parenthesis around “(99.9% of)” from the disinfection qualifier or remove “[Eliminates]”.